Pre- and Post-Vaccination Serologic Testing Guidelines for Hepatitis B

Washington State Clinical Laboratory Advisory Council
Originally published: October, 2000 Reviewed: March 2005

FOR EDUCATIONAL PURPOSES ONLY
The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

Pre-vaccination Testing

Anti-HBc total, total antibody (i.e., IgM and IgG) to the hepatitis B core antigen is an indicator of a current or previous HBV infection. It is also used with anti-HBs and HBsAg for screening at-risk populations for hepatitis B to determine their immune status. Individuals found to be positive for both anti-HBc and anti-HBs are presumed to be immune by prior natural infection. Those found to be negative are at risk for HBV infection and should be recommended for vaccination.

Post-vaccination Testing

The level of circulating anti-HBs is used to determine the effectiveness of vaccination. The hepatitis B vaccine is designed to induce only anti-HBs (the protective antibody) and will not induce an anti-HBc response. Outside the US, other levels of antibody may be used to determine immunity. These levels may vary from country to country.

The minimum protective level of anti-HBs is 10 IU/ml.

Post vaccination testing is advised only for:

1. Persons whose clinical management depends on knowledge of their immune status (e.g., infants born to HbsAg-positive mothers, dialysis patients, patients with HIV infection), and
2. Persons at occupational risk (dialysis and other health care workers).
3. Persons who are non-responders to the vaccine are usually candidates for revaccination (e.g., repeat 3-dose series) and post-vaccination retesting.

Also, older age, obesity, heavy smoking, and gluteal administration have been associated with lower antibody responses to vaccination.

Following vaccination, antibody titers may diminish over time, and may fall below the limits of detection by standard immuno-assays. However, there has not been documentation of clinical HBV infection or chronic infection among vaccinated adults who were exposed to HBV many years after primary vaccination. Thus, protective immunity may be life-long due to an anamnestic immune response to HBV, and currently the CDC does not recommend a late booster dose of HBV vaccine. Nevertheless, if a vaccinated person has a documented exposure to Hepatitis B, and titers are undetectable at the time of exposure, it is reasonable to offer HBIG and a booster dose of vaccine to the exposed individual.

In hemodialysis patients, it is recommended to test antibody levels annually and a booster dose given if the titer is <10 mIU/ml.

References:

1. Abbott Laboratories, Abbott Diagnostics Educational Services, Hepatitis Learning Guide, 1998
2. MMWR, Vol. 40/No. RR:13, November 22, 1991
3. Mandell, GL et al, eds. Principles and Practice of Infectious Diseases, 4th Edition, New York; Churchill Livingstone, p.1428
4. George, Sarah, M.D. and Stapleton, Jack T., M.D., The Status of Viral Hepatitis Vaccines, Clinical Microbiology Newsletter, Vol. 21, No. 14, July 15, 1999, p.113 – 118
5. CDC. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1991;40(RR-13);1-19

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